

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses

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Multifocal intraocular lenses

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 11979-9:2006 sisaldab Euroopa standardi EN ISO 11979-9:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 27.10.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 11979-9:2006 consists of the English text of the European standard EN ISO 11979-9:2006.</p> <p>This document is endorsed on 27.10.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. distant and near).</p>	<p>Scope:</p> <p>This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. distant and near).</p>
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ICS 11.040.70

Võtmesõnad:

ICS 11.040.70

English Version

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal
intraocular lenses (ISO 11979-9:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9:
Lentilles intraoculaires multifocales (ISO 11979-9:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 9:
Multifokale Intraokularlinsen (ISO 11979-9:2006)

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Foreword

This document (EN ISO 11979-9:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.

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Endorsement notice

The text of ISO 11979-9:2006 has been approved by CEN as EN ISO 11979-9:2006 without any modifications.

**Ophthalmic implants — Intraocular
lenses —**

**Part 9:
Multifocal intraocular lenses**

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 9: Lentilles intraoculaires multifocales*



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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

- *Part 1: Vocabulary*
- *Part 2: Optical properties and test methods*
- *Part 3: Mechanical properties and test methods*
- *Part 4: Labelling and information*
- *Part 5: Biocompatibility*
- *Part 6: Shelf-life and transport stability*
- *Part 7: Clinical investigations*
- *Part 8: Fundamental requirements*
- *Part 9: Multifocal intraocular lenses*
- *Part 10: Phakic intraocular lenses*

Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. far and near).

NOTE The term “near vision” as used in this part of ISO 11979 includes useful vision at a distance of claimed benefit; e.g. near and/or intermediate distances.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1, ISO 14155-1 and ISO 14155-2 apply.